Department of Veterans Affairs

Memorandum

Date: April 23, 2009

From: Administrative Investigation Board (AIB)

Subj: Report of Investigation into Issues Related to Endoscope Reprocessing at the Miami VA Medical Center.

To: Network Director, VISN 8 (10N8)

PRELIMINARY STATEMENT

The Administrative Investigation Board (AIB) has completed its investigation as directed by your memorandum dated March 23, 2009 *(Attachment 1)*.

1. Scope.
This investigation was convened to conduct a thorough review of endoscopy practices at the Miami Veterans Affairs Medical Center (VAMC) to include:

- Procedures for selecting and placing endoscopy equipment and supplies into use.
- Procedures for setting up and using endoscopy equipment.
- Procedures for processing endoscopy equipment.
- Communication among involved programs about equipment inventory, processing endoscopes and maintenance.
- Procedures for placing equipment out of service when suspicion of gaps in processing occurs.
- Procedures for educating and training staff in setting up, using and maintaining endoscopy equipment.
- Procedure to respond to recalls and alerts.
- Practices prior to the issuance of Patient Safety Alert 09-07, as well as the medical center's response to the Alert.

2. Summary list of witnesses interviewed:

a. [redacted], GI Technician
b. [redacted], GI Nurse
c. [redacted] Supply, Processing and Distribution Technician
d. [redacted], GI Nurse Liaison
e. [redacted], Nurse Manager
f. [redacted] Quality Management Performance Improvement Specialist for Medical Service
g. [redacted] Infection Control Practitioner

h. [redacted], Chief, Supply, Processing, and Distribution Section
i. [redacted], Chief, Acquisition and Materiel Management Service
j. [redacted], Chief, Biomedical Engineering Service
k. [redacted], Chief, Gastroenterology Section
l. [redacted], Patient Safety Coordinator
m. [redacted], Biomedical Engineering Technician (written statement)

3. Significant procedural issues.

a. On March 31, 2009, at the request of the AIB, a meeting was held with the Convening Authority to discuss the scope of the charge letter. The AIB required clarification on the span of the scope, which was clarified as pertaining to GI Endoscopy. However, it should be noted that conclusions should be examined in context with respect to all areas of endoscopy.

b. On April 1, 2009, the AIB contacted the Miami VA Medical Center Director and the Chief of Staff to convey concerns related to the ongoing reprocessing of endoscopes. Subsequently, the Veterans Integrated Service Network (VISN) 8 scheduled a conference call for 8:30 am on April 2, 2009 to discuss the AIB's position with other staff from the VISN and VA Central Office (VACO). During this call, the AIB described in detail our observations and position. The VISN 8 Chief Medical Officer (CMO) requested a written statement from the AIB, summarizing our position on the ongoing reprocessing of endoscopes. On April 2, 2009, the following statement was sent via email *(Attachment 2)* to the convening authority:

> "Per your request,
>
> The AIB Board has determined through testimony, observation, and record review that endoscope reprocessing at the Miami VA Medical Center is incomplete and not according to device specific manufacturer's instructions. Endoscopes should not be used until personnel assigned to reprocess equipment receive device-specific reprocessing training and demonstrate compliance with manufacturer's reprocessing instructions. Competency must be verified by a deemed expert in endoscope reprocessing through direct observation.
>
> This summarizes a position of the Board."

In addition, the VISN 8 CMO requested that the observations discussed on the conference call be placed in written format for review by VACO *(Attachment 3)*. This was completed and sent in draft form on April 2, 2009 *(Attachment 4)*.

A cross reference to specific manufacturers' instructions was requested *(Attachment 5)* to be added to the written observations, which was provided to the Convening Authority on April 6, 2009 *(Attachment 6)*.

c. On April 3, 2009, the AIB discussed an apparent safety concern with the EndoGator system from Byrne Medical, Inc., and specifically the EndoGator Auxiliary Water Jet Connector for Olympus Endoscopes, part number 100115 *(Attachment 14, part with metal; Exhibit HH)*. At the time of our investigation, the system was no longer in use at the Miami VAMC. The concerns were reported to the VISN 8 CMO and to Lori King, Biomedical Engineer at the National Center for Patient Safety.

FINDINGS OF FACT

Guidance and policies.

4. The Veterans Health Administration (VHA) Directive that governs use and reprocessing of reusable medical equipment (RME) in VHA facilities is Directive 2009-004, Use and Reprocessing of Reusable Medical Equipment (RME) in VHA Facilities, dated February 9, 2009 *(Exhibit II)*.

5. VA Directive/Handbook 7176, Supply Processing, and Distribution (SPD) Operational Requirements, dated August 16, 2002 *(Attachment 16)*.

6. Memo from the Under Secretary for Health, subject "Proper Sterilization of Equipment," dated February 9, 2009 *(Attachment 17)*.

7. Memo from Principal Deputy Under Secretary for Health (10A) and Deputy Under Secretary for Health for Operations and Management (10N), subject "Endoscopy Step Up Week," dated February 4, 2009. *(Attachment 18)*.

8. Memo from Deputy Under Secretary for Health for Operations and Management, subject "Review of Reprocessing of Endoscopic Equipment," dated January 28, 2009. *(Attachment 19)*.

9. Medical Center Policy Memorandum No. 00-30-04, Equipment Committee, dated July 16, 2004, establishes a committee to provide integration of the equipment planning process and the strategic planning of the Medical Center *(Exhibit O)*.

10. Medical Center Policy Memorandum No. 002B-01-05, Medical Equipment Management Plan, dated August 3, 2005, describes procedures for placing medical equipment into use and for providing ongoing support. In addition, it describes responsibilities for equipment recalls, hazard alerts and patient safety alerts. Supply, Processing, and Distribution (SPD) Section of Acquisition and Materiel Management Service (A&MMS) is responsible for recalls and hazard alerts, and Quality Management and Performance Improvement is responsible for patient safety alerts *(Exhibit P)*.

11. Medical Center Memorandum No. 00-96-01, dated September 14, 2001, establishes the Miami VAMC's procedures and responsibilities for Patient Safety Alerts *(Exhibit LL)*.

12. Medical Center Policy Memorandum No. 05-76-00, Competency Assessment, dated September 28, 2000, describes the process to assess/verify education/training needs and other interventions needed to enable achievement of optimal organization employee competence *(Exhibit Q)*.

Procedures for selecting and placing endoscopy equipment and supplies into use, and placing equipment out of service when suspicion of gaps in processing occurs.

13. The [redacted] has been in [redacted] current position since July 2008 in an Acting role and officially since December 15, 2008 *(Exhibit Z page 3 line 21 through page 4 line 4)*.

14. The [redacted] has been in [redacted] position since February, 2009 *(Exhibit Y page 3 line 21)*.

15. The [redacted] does not have an Assistant Chief currently *(Exhibit Z page 40 line 17)*.

16. The [redacted] has been in [redacted] position since August 2004 *(Exhibit AA page 4 line 1)*.

17. The [redacted] has had approximately five (5) different supervisors in as many years. [redacted] originally reported to the Assistant Director, who changed three times, then the Associate Director who recently retired, and now reports to an Acting Associate Director *(Exhibit AA page 33 lines 4-11)*.

18. The [redacted] gets along well with the [redacted] and there is a common understanding of the issues they are working to correct, with regard to inventory control and management *(Exhibit AA page 28 line 10 through page 29 line 15)*.

19. The [redacted] when placed in [redacted] new position, found that the Equipment Inventory Lists (EIL) were a disaster. Only recently, has Research Service provided A&MMS access to all of their assigned space for inspection, and lost equipment is still being found. A major effort to improve inventory accuracy was done in December 2008. There is reservation on whether the Information Technology Service inventory will ever get better *(Exhibit Z page 34 line 12 through page 37 line 11)*.

20. The [redacted] at the time) was asked to an Equipment Committee Meeting in January 2008 for the first time and was asked to take over the Committee the following day. [redacted] found that there had been no minutes and that [redacted] was starting from scratch. [redacted] first Committee meeting was August 2008 *(Exhibit Z page 27 line 4 through page 28 line 4)*.

21. Prior to 2004, A&MMS unilaterally controlled the Automated Engineering Management System/Medical Equipment Reporting System (AEMS/MERS) and Biomedical Engineering Service ran a separate system of inventory and hard copy maintenance records. The Biomedical Engineering Service system was abandoned in 2004 and Biomedical Engineering Service has been working with A&MMS to correct and utilize the existing AEMS/MERS records. Currently, A&MMS controls the Equipment Category field, and while Biomedical Engineering Service does have access, they rely on A&MMS to make changes to errors identified by Biomedical Engineering Service *(Exhibit AA page 17 line 8 through page 23 line 3).*

22. Medical equipment maintenance records were kept on index cards up until two to three years ago *(Exhibit AA page 15 line 11-15).*

23. The [redacted] believes that there are serious process and inventory control issues at the Miami VAMC *(Exhibit AA page 31 line 16 through page 32 line 1).*

24. Biomedical Engineering Service has previously identified an electroencephalography machine that was called a "hard drive" in AEMS/MERS. In order to correct this, an email was needed to be sent to A&MMS and then they would print the label and bring it to Biomedical Engineering Service at some later time *(Exhibit AA page 20 line 19 through page 21 line 6).*

25. There are three equipment entry numbers for the Medivators Endoscope Reprocessors, but there are only two reprocessors. Biomedical Engineering Service determined that an equipment entry number for an "active vapor management system" was inadvertently placed on one of the Medivators Endoscope Reprocessors *(Exhibit KK page 2).*

26. The [redacted] estimates that 20% of the time, equipment is delivered directly to users without going through Biomedical Engineering Service, especially if equipment gets mistakenly ordered on a credit card *(Exhibit AA page 26 line 11 through page 27 line 6).*

27. The [redacted] is not sure how endoscopes are getting into the inventory and has been having difficulty for the last two and a half to three years, writing a service contract for Olympus partially because of the incomplete inventory. The [redacted] has a confidence in the endoscope inventory of less than 50% *(Exhibit AA page 27 line 11 through page 28 line 9).*

28. Previous to the [redacted], equipment would be delivered straight to using services. Only recently has the policy been enforced *(Exhibit Y page 15 line 9 through page 16 line 9).*

29. The [redacted] states it is rare that equipment is found in the Medical Center that isn't in the inventory *(Exhibit Y page 21 line 11-21).*

30. "Things coming in through the back door" is described as a major problem, with vendors having access to the Medical Center without going through A&MMS *(Exhibit Z page 29 lines 4-14).*

31. Currently, vendors have access to the Medical Center by reporting to Police Service and are able to leave samples, which is causing "a nightmare" *(Exhibit Z page 29 line 15 through page 30 line 13).*

32. The [redacted] reports that vendors are required to go through SPD prior to accessing the OR *(Exhibit Z page 31 line 3 through page 34 line 6).*

33. The endoscope inventory maintained by SPD Section was revised on March 25, 2009 and contains forty-one (41) line items. The inventory list contains serial numbers but does not contain equipment entry numbers *(Exhibit B).*

34. The SPD inventory list of endoscopes, created on March 25th, was their independent effort to create a physical inventory. It had not been matched with AEMS/MERS and not every discrepancy has been accounted for *(Exhibit Y page 39 line 11 through page 42 line 17).*

35. The AIB extracted data from AEMS/MERS showing scopes, reprocessors, and the Olympus Flushing Pumps that were designated as "in use" *(Exhibit NN).*

36. A comparison of inventory records showed numerous discrepancies between inventory maintained by SPD, A&MMS, and inventory on a maintenance contract quote from Olympus, which reflects fifty-six (56) items *(Exhibit JJ).* A summary of differences was compiled by the AIB *(Exhibit NN).*

37. There is little to no understanding by the GI Nurses as to who is responsible for introducing equipment into the work site, or how that is accomplished *(Exhibit R page 17 lines 5-15;).*

38. The [redacted] came to understand that the EndoGator system had not been approved for use by the organization, which was part of [redacted] decision making to take it out of service *(Exhibit BB page 22 lines 3-8).*

39. The [redacted] verified that the EndoGator system *(Attachment 14)* had not been approved by the Commodity Standards Committee and when the [redacted] had two left, needing to order more, [redacted] was told that it needed to be approved prior to ordering more *(Exhibit Y page 35 line 9 through page 36 line 20).*

Procedures for setting up, using, and processing endoscopy equipment.

40. Employees having responsibility for endoscope set up, precleaning, and reprocessing, have disparate supervisory chains of command. The SPD Technicians, responsible for reprocessing endoscopes have a supervisory chain of command to the Chief, A&MMS; GI Technicians, responsible for equipment set up and precleaning, report directly to the Chief, Gastroenterology; and the GI Nurses report directly to the Nurse Manager (2.e.) *(Exhibit T page 9 lines 14-20; Exhibit X page 5 lines 2-3 & page 9 lines 18-21; Exhibit BB page 5 lines 6 through page 6 line 17).*

41. In the absence of a GI Technician, the GI Nurses fill in for endoscope set up and precleaning, which occurs approximately once every four or five months for every GI Nurse *(Exhibit S page 5 lines 7-15; Exhibit BB page 4 lines20-22 & page 5 lines 1-3).*

42. The [redacted] is directly responsible for the GI Nurses, but does not believe [redacted] has responsibility for technical issues *(Exhibit X page 10 lines 11-12).*

43. The [redacted] responsible for GI Endoscopy, is also supervising the pain clinic, ambulatory surgery, the radiology nurses, the IV team, and used to supervise cardiac catheterization nurses. [redacted] coordinates work through Nurse Liaisons in each area *(Exhibit X page 4 lines 6-13).*

44. The [redacted] has not been directly instructed to ensure that procedures are according to manufacturers' instructions, but [redacted] feels it is [redacted] responsibility *(Exhibit U page 51 lines 2-16).*

45. The [redacted] has never set up a scope, taken it down, or been involved in the precleaning of the endoscopes *(Exhibit U page 21 lines 11-16 & page 22 lines 6-17 & page 24 lines 17-21 & page 26 lines 3-14).*

46. Oversight of the endoscope equipment work performed by the GI Nurses and GI Technicians is largely done by non-supervisory employees or not at all *(Exhibit R page 13 lines 3-22 & page 14 lines 1-12; Exhibit S page 9 lines 4-16).*

47. The [redacted] is also assigned responsibility for oversight of GI Technicians *(Exhibit BB page 6 lines 4-17)*

48. GI Technicians and GI Nurses do not routinely read manuals, but go more on experience *(Exhibit U page 50 lines 7-20 & errata sheet 2 line 12).*

49. Prior to March 2009, the GI Nurses did not have standard operating procedures *(Exhibit R page 12 lines 15-18; Exhibit S page 6 lines 4-8; Exhibit U page 52 lines 2-7).*

50. The GI Nurses and GI Technicians had not been instructed to reprocess the MAJ-855 tubing. The first explanation of this incorrect procedure was subsequent to a visit by Byrne Medical, Inc., who pointed out alerts by Olympus and offered the EndoGator

system *(Attachment 14)* as an alternative that can be changed every 24 hours, with a backflow valve changed every procedure. The MAJ-855 had already been taken out of service *(Exhibit R page 17 lines 16-22 & page 18 lines 1-12; Exhibit S page 10 lines 19-22 & page 11 lines 1-3).*

51. On March 27 and 28, 2009, the [redacted] working in GI, processed a total of 51 or 52 endoscopes. The endoscopes were previously clean, but were tested for quality assurance purposes. When [redacted] arrived to reprocess the scopes, [redacted] found them improperly stacked and stored *(Exhibit T page 27 lines 6-20 & page 28 lines 4-12).*

52. The [redacted] working in GI processes between four (4) and twenty (20) scopes a day *(Exhibit T page 24 lines 19-22 & page 25 lines 1-3).*

53. The [redacted] working in GI maintains the disinfectant efficacy monitoring log *(Exhibit I)* on a daily basis. Monitoring is not done between each reprocessed scope *(Exhibit T page 36 lines 12-22 & page 37-38 & page 39 lines 1-15).*

54. The [redacted] describes in detail the testing of the clean scopes on Thursday, March 26, 2009 *(Exhibit W page 12 line 10 through page 17 line 11).*

55. The [redacted] is not aware of any previous reports of debris coming out of the scopes after cleaning *(Exhibit W page 17 lines 12-18).*

56. Endoscopes from the OR are also reprocessed by SPD *(Exhibit Y page 65 lines 6-16).*

57. The reported malfunctioning endoscope reprocessor that was only printing two rinse cycles was the newer endoscope reprocessor, DSD-201. Biomedical Engineering Service worked with the manufacturer, Minn Tech, and determined that the endoscope reprocessor was programmed correctly, but the incorrect program for two rinses was selected. There are a total of 9 different programs that can be selected *(Exhibit KK; Exhibit AA page 14 lines 2-11).*

Communication among involved programs about equipment inventory, processing endoscopes and maintenance.

58. In reference to equipment and supplies, staff members use various terms for the same thing, depending on their area of expertise, which causes unclear communication *(Exhibit Z page 23 line 18 through page 24 line11).*

59. Infection Control does not observe reprocessing procedures done by SPD *(Exhibit W page 19 line 14-16).*

60. After reviewing reprocessing procedures in Bay Pines first hand, [redacted] understood the process to be very complex. More so than originally thought *(Exhibit AA page 10 lines 13-16)*.

61. The [redacted] reports that Biomedical Engineering Service promptly responds to requests for service *(Exhibit T page 32 lines 10-21)*.

62. The [redacted] was not contacted by anyone, and is not aware of anyone in his service being contacted, to discuss Patient Safety Alert 09-07, prior to A&MMS responding to the alert *(Exhibit BB page 11 line 22 through page 13 line 17 & page 16 line 22 through page 17 line 6)*.

63. The [redacted] working in GI is not aware of who is responsible for the quality of his work *(Exhibit T page 35 lines 7-12)*.

64. [redacted], first became aware of Patient Safety Alert 09-07 during a SPD in-service meeting. Because [redacted] was late to the meeting, [redacted] was asked to read the Patient Safety Alert to the group and lead the discussion on it. [redacted] mainly stays in the reprocess room and has never set up the procedure room for the GI Technicians. [redacted] did not know what pump or tubing the Patient Safety Alert 09-07 was referring to and explained at the in-service that [redacted] doesn't use anything like that in his reprocessing. *(Exhibit T page 17 lines 17-22 & pages 18-19 & page 20 lines 1-20)*.

65. The [redacted] working in GI expressed previous concerns related to endoscope reprocessor "B" having a discrepancy between the programmed three (3) rinses and the printed receipt showing only two (2) rinses. [redacted] explained that Biomedical Engineering Service reported that the endoscope reprocessor was in-fact going through three (3) rinses, despite the discrepancy. In addition, [redacted] reported concerns over the amount of alcohol the endoscope reprocessor was using. [redacted] manually added additional alcohol into the scopes in order to compensate *(Exhibit T page 31 lines 16-15 & 31 lines 21-22 & page 32 lines 1-4)*.

66. The older endoscope reprocessor, DSD-91E, received a three rinse upgrade to it in May 2006 *(Exhibit KK; Exhibit AA page 13 line 10 through page 14 line 11)*.

67. Work orders in Biomedical Engineering Service are received both via telephone calls and electronically, to include direct contact with technicians. Biomedical Engineering Service is responsible for documentation of work *(Exhibit AA page 15 line 16 through page 16)*.

68. The [redacted] was not aware of the discrepancy between the printout and programmed rinse cycles of one of the reprocessors until March 31, 2009. The reprocessor in question was verified to be the newer reprocessor, DSD-201. The [redacted] reports that there are 9 programs that can be selected and that an incorrect program may have been selected for 2 rinse cycles *(Exhibit KK)*.

69. Biomedical Engineering Service does not replace filters on the DSD-91E and DSD-201 endoscope reprocessors. Both reprocessors are scheduled for semi-annual preventive maintenance by Biomedical Engineering Service. *(Exhibit AA page 35 lines 12-13; Exhibit UU).*

Procedures for educating and training staff in setting up, using and maintaining endoscopy equipment.

70. The [redacted] does not provide direct training to the GI Technicians and has no knowledge of precleaning or set up *(Exhibit BB page 8 lines 1-2 & page 9 line 19 through page 10 line 4 & page 23 lines 16-18).*

71. The [redacted] responsible for GI has never had training or read material about endoscope processing *(Exhibit X page 6 lines 5-8).*

72. The [redacted] did not have orientation or training on device specific instructions for endoscope set up or precleaning. Knowledge, skills, and abilities, were based on previous experience and preceptor training *(Exhibit U page 6 lines 18-22 & pages 7-8 & page 9 lines 1-13 & page 10 lines 2-7 & page 21 lines 11-16).*

73. GI Nurses have not received training or orientation to duties related to endoscope set up and precleaning. In one case, the determination of competency was based on experience at a previous facility *(Exhibit R page 11 line 22 & page 12 lines 1-8; Exhibit S page 5 lines 19-22 & page 6 lines 1-17 & page 7 lines 7-22 & page 8 lines 1-8 & page 9 lines 17-22 & page 10 lines 1-12; Exhibit BB page 7 line 2 through page 8 line 2).*

74. The [redacted] working in GI was hired approximately one and half years ago. [redacted] training for reprocessing scopes consisted of observing for one week and being supervised for one week by the prior [redacted] before performing his duties independently. In addition, [redacted] had access to manuals. *(Exhibit T page 7 lines 3-22 & page 8 lines 1-19).*

75. The [redacted] performing reprocessing of endoscopes have only received infrequent spot checks of their work by supervisors in their chain of command and non-supervisors not in their chain of command. The [redacted] and Infection Control have observed the entire process, but have no background or training in reprocessing *(Exhibit T page 11 lines 7-22 & page 12 lines 1-9 & page 35 lines 13-22 & page 35 lines 1-6).*

76. SPD Technicians' competencies are completed by the [redacted] *(Exhibit T page 40 lines 8-11, Exhibit DD & EE).*

77. SPD GI Technicians and [redacted] competency assessments are general in nature and refer to safe operation of equipment, not for device-specific procedures. There is no recorded evaluation for FY08, just an

evaluator's signature. Documentation on the 12-22-08 training for the Patient Safety Alert, is signed by the employee, but has no recorded evaluation or signatures by preceptor/manager/supervisor *(Exhibit DD, EE, & FF)*.

78. The [redacted] responsible for the competencies of the SPD Technicians, has self certified [redacted] own competency related to the sterilizer competencies *(Exhibit FF)*.

79. GI Nurses fill in for GI Technicians at times, but competencies on endoscope precleaning are not performed by the [redacted]. [redacted] relies on their experience *(Exhibit X page 12 line 12 through page 14 line 15)*.

Procedures to respond to recalls and alerts.

80. The [redacted] (2.f.) understands that the [redacted] is responsible for managing Patient Safety Alerts *(Exhibit V page 6 lines 12-15)*.

81. The [redacted] for Medical Service (2.f.) does not feel that a good process is in place for handling Patient Safety Alerts *(Exhibit V page 12 line 8-13)*.

82. The [redacted] understands that the facility recall coordinator is the [redacted] *(Exhibit W page 8 line 9-17)*.

83. The [redacted] thinks [redacted] is copied on all Patient Safety Alerts but isn't sure *(Exhibit W page 22 lines 11-22)*.

84. The [redacted] does not read every Patient Safety Alert in detail. A summary review is made to determine if [redacted] should have any involvement *(Exhibit W Page 24 lines 7-22 & page 25 lines 1-4)*.

85. The [redacted] is the Facility Recall Coordinator *(Exhibit Y page 9 lines 5-18)*.

86. The [redacted] is the backup recall coordinator to the [redacted] *(Exhibit Z page 4 lines 15-20)*.

87. The [redacted] understands that a Recall policy exists, but is unsure who the designated recall coordinator is *(Exhibit AA page 6 line 6 through page 7 line 12)*.

88. The [redacted] is not aware of the process for responding to Patient Safety Alerts *(Exhibit U page 55 lines 4-5)*.

89. The [redacted] understands that Patient Safety Alerts are [redacted] responsibility and that recalls are the responsibility of the recall coordinator who is the [redacted] *(Exhibit CC page 4 lines 3-19).*

90. The [redacted] sends all Patient Safety Alerts to individuals directed by the alert and sometimes expands the list of recipients. In addition, [redacted] briefly narrates on the emails what the alert is about out of concern that recipients will not open the attachments *(Exhibit CC page 4 line 20 through page 6 line 7; Exhibit K).*

91. The process for responding to Patient Safety Alerts, recalls, and action items can have dual processes for completion *(Exhibit CC page 10 line 10 through page 11 line 16).*

92. The [redacted] felt the Patient Safety Alert structure was problematic, although not an excuse for not reading the entire alert *(Exhibit CC page 23 lines 7-22; Exhibit Y page 71 lines 10-19).*

Practices prior to the issuance of Patient Safety Alert 09-07, as well as the medical center's response to the Alert.

93. The MAJ-855 tubing, used for the endoscope auxiliary water channels and with the Olympus Flushing Pump was not processed between patients *(Exhibit R page 8 lines 8-14; Exhibit AA page 4 lines 12-15;)*

94. In the last year and a half, endoscope reprocessing procedures have not changed *(Exhibit T page 13 lines 8-19).*

95. The MAJ-855 auxiliary water tubing is supposed to be used for both set up and precleaning in the procedure room. *(Exhibit T page 17 lines 17-22; Exhibit OO).*

96. The first time you see the MAJ-855 entered into the purchasing system is March 5, 2009 *(Exhibit Z page 7 lines 9-11).*

97. Standard operating procedures related to reprocessing were put in place March 23, 2009 *(Exhibit U page 53 lines 6-11).*

98. The [redacted] believes 70% of endoscope damage requiring repair is caused by mishandling. Scopes are dropped off in Biomedical Engineering Service and stacked inappropriately. A significant amount of money is being spent on repairs ($250,000/year) and it has been a battle to get the organization to recognize that there is an issue *(Exhibit AA page 30 line 10 through page 31 line 15; Exhibit UU).*

99. The [redacted] working in GI had not seen the Olympus Safety Alerts which are Exhibits E & F *(Exhibit T page 34 lines 3-12).*

100. The [redacted] distributed Patient Safety Alert 09-07 to the organization for the first time via e-mail on December 24, 2008. It was sent out for informational purposes for all individuals with an understanding that the [redacted] had responsibility for responding *(Exhibit K; Exhibit CC page 12 line 17 through page 13 line 11; Exhibit MM).*

101. The [redacted] received the Patient Safety Alert 09-07 for action via email from the [redacted] on December 24, 2008 and was immediately read by the [redacted] It was responded to by the [redacted] on January 5, 2009 *(Exhibit MM).*

102. The [redacted] ran a search in the item master file for the MAJ-855 tubing and did not find it. [redacted] knew that his SPD Technician (2.c.) used the Olympus Washing Tube, MH-974 for reprocessing. [redacted] states that "word got back to us" that the pump was not used in the GI station. This information was used to report on the Patient Safety Alert *(Exhibit Y page 10 line 13 through page 12 line 10).*

103. Regarding the Patient Safety Alert 09-07, the [redacted] had reported to the [redacted] "no" on all three action items. Concerned about the response not having any explanation, the [redacted] talked directly to the [redacted] who once again said that he ran a search on the inventory for the MAJ-855 and did not find it. [redacted] also reported that someone at the GI station reported that they did not have the pump. The [redacted] also ran a search [redacted] to check for the MAJ-855 *(Exhibit Z page 5 line 7 through page 7 line 11 & page 10 line 12 through page 13 line 13).*

104. The [redacted] was not satisfied with the initial response from the [redacted] regarding Patient Safety Alert 09-07 because it was too abbreviated. [redacted] asked for more documentation to show that all three action items were completed. This is when [redacted] was told that GI reported to A&MMS that they did not have the pumps and that the MAJ-855 had never been ordered, which was described as more evidence to the fact they did not have the pumps *(Exhibit K; Exhibit MM; Exhibit CC page 13 line 12 through page 15 line 13).*

105. The [redacted] received the original routing of Patient Safety Alert 09-07 from the Patient Safety Coordinator (2.l.), but did not understand that [redacted] had any responsibility for it, and no one contacted [redacted] about it prior to the facility response to the alert *(Exhibit MM; Exhibit BB page 15 line 3 through page 16 line 2).*

106. The [redacted] read Patient Safety Alert 09-07, but did not understand the technical aspects of it. [redacted] and the [redacted] relied on the [redacted], for a determination of compliance *(Exhibit BB page 17 line 7 through page 18 line 3).*

107. The [redacted] gave the Patient Safety Alert to his senior staff and states [redacted], did not deal with the reprocessing issue, and

only determined that the correct tubing was being used *(Exhibit BB page 16 line 11 through page 17 line 6).*

108. The [redacted] forwarded the Patient Safety Alert 09-07 to the [redacted] for a determination if a problem existed or not *(Exhibit X page 6 lines 12-21).*

109. The [redacted] first became aware of Patient Safety Alert 09-07 when one of the [redacted] brought it to [redacted] attention. At this time [redacted] only confirmed that they were using the correct tubing. *(Exhibit U page 13 lines 17-22 & page 14 lines 1-16).*

110. The [redacted] first became aware of the MAJ-855 reprocessing issue when the representative from Byrne Medical, Inc. made a visit on February 13, 2009 and brought the Olympus Safety Alerts *(Exhibits E&F).* The EndoGator system was introduced as an alternative to the MAJ-855 *(Exhibit U page 17 lines 3-19).*

111. The [redacted], as part of GI step-up week, reviewed Patient Safety Alert 09-07 a second time and made a point to "really go through everything", "fully through", which is when [redacted] first understood that reprocessing of the MAJ-855 was also being addressed in the Patient Safety Alert *(Exhibit U page 15 lines 1-13 & page 17 lines 4-10 &Exhibit GG).*

112. The [redacted] is unaware of why the Medical Center reported compliance with Patient Safety Alert 09-07 and states that no one discussed it with [redacted] is not aware of who was responsible for responding to the Patient Safety Alert *(Exhibit U page 33 lines 8-22 & page 34 lines 1-14; Exhibit U errata sheet line 20).*

113. The [redacted] was not aware of Patient Safety Alert 08-13 or 09-07 until March 5, 2009 *(Exhibit V page 4 lines 1-18).*

114. The [redacted], recalls seeing Patient Safety Alert 09-07 because [redacted] was copied on it and engaged in determining if the Medical Center had responded sometime in February. Testimony also shows that [redacted] supervisor, [redacted] was also questioning if the Patient Safety Alert had been responded to *(Exhibit W page 6 lines 7-22 & page 7 & page 8 lines 1-4).*

115. The [redacted], was told that the Medical Center did not have the pump and the [redacted] said that the tubing had never been ordered, therefore [redacted] conclusion was that the Patient Safety Alert did not apply to Miami *(Exhibit W page 10 lines 11-22).*

116. The [redacted] remembers Patient Safety questioning the [redacted] as to how [redacted] knows the pump isn't used, and the response was that the tubing had never been purchased *(Exhibit W page 11 lines 15-20).*

117. The [redacted] is not aware of who reported compliancy with Patient Safety Alert 09-07, but thought GI staff told SPD that "we are not using the tubing." *(Exhibit X page 15 line 1-8).*

118. The [redacted] was under the impression that SPD is who reported the Medical Center compliant with the patient safety alerts and not the GI staff *(Exhibit AA page 5 lines 16-19).*

119. The [redacted] did not recall seeing Patient Safety Alert 08-13, but did remember seeing Patient Safety Alert 09-07 sometime towards the end of January. [redacted] recalls receiving it from the VISN via email as part of preparation for a group visit to Bay Pines VAMC *(Exhibit AA page 8 lines 2-9 & page 9 lines 1-11 & page 10 lines 1-5).*

120. On March 4, 2009, the [redacted] walked into a meeting in preparation for the "Safety Step-Up Week" and overheard the [redacted] saying "Patient Safety isn't going to be happy with that." They found out that GI was using the EndoGator system in place of the MAJ-855 tubing which had not been approved by the Commodity Standard Committee. The EndoGator system also meant that GI did have the Olympus Flushing Pump, which was a surprise to everyone *(Exhibit CC page 16 line 14 through page 17 line 8).*

121. On March 5, 2009, the [redacted] and several others, made a visit to the GI Station. Staff in GI were adamant that there was no problem. The [redacted] pointed out that there were more issues than just the tubing, which was described on the second page of the Patient Safety Alert. It was at this time, the GI staff began to understand there was more to the alert than they had dealt with up until that time *(Exhibit CC page 17 line 15 through page 19 line 7).*

122. The Medical Center Director assigned individuals to participate in the Endoscopy Step Up Week exercises, to take place on March 12 and 13, 2009 *(Exhibit GG).*

123. The EndoGator system was used after February 13, 2009 and was only used eight (8) times. The entire system was disposed of at the end of each day and not between patients *(Exhibit U page 30 lines 8-22 & page 31 lines 1-11; Exhibit U errata sheet line 19; Exhibit V page 9 lines 9-14 & errata sheet line 5; Exhibit W page 19 lines 19-22 & page 20 lines 1-8; Exhibit BB page 10 lines 5-10; Exhibit HH; Exhibit TT; Attachment 14).*

124. The [redacted] made the decision to no longer use a mechanical flushing device until all of the issues could be sorted out, which resulted in the removal of the EndoGator system. [redacted] believes this decision was made on March 4. The device was physically removed from the area on March 12, 2009, but was not used between March 4th and the 12th *(Exhibit BB page 10 lines 5-22 & page 20-22 & page 25 line 16 through page 26 line 2).*

125. The EndoGator system is labeled for 24 hour use, with replacement of the backflow valve between procedures, and the manufacturer states that it is functionally equivalent to an Olympus MAJ-855. A Validation Protocol for the 24-hour use was conducted by Nova Biologicals, Inc. *(Exhibit HH; Attachment 14).*

126. On March 26, 2009, an Olympus representative came to the facility to provide an in-service on the MAJ-855 and Olympus Flushing Pump. When flushing a clean scope, debris was found in the auxiliary water channel. Other clean scopes were also tested and debris was also found. All of the scopes were then tested *(Exhibit U page 37 lines 6-20 & errata sheet line 25-26 & page 38-39 & errata sheet 2 line 4 & page 40 lines 1-16 & errata sheet 2 line 5; Exhibit V page 19 lines 7-22 & page 20 lines 1-4; Exhibit W page 30 lines 18-20; Exhibit X page 20 lines 8-13).*

127. The [redacted] was present for the testing of the clean scopes and documented the results *(Exhibit X page 23 lines 5-6).*

128. The [redacted] describes the visit by the Olympus representative on March 26, 2009 as a demonstration of the precleaning and reprocessing. A nurse needed to leave to get a patient ready, and was asked by the [redacted] to go ahead and demonstrate the process. It is when [redacted] manually flushed the clean scope that the debris was discovered *(Exhibit X page 19 lines 4-8; page 19 lines 9-22 and page 20 lines 1-13).*

CONCLUSIONS

Procedures for selecting and placing endoscopy equipment and supplies into use, and placing equipment out of service when suspicion of gaps in processing occurs..

CONCLUSION 1: Supervisory turnover, related to medical equipment management, has hindered the necessary actions to correct a history of inadequate inventory control.

ANALYSIS:

1. The principal Service Chiefs responsible for the proper management of medical equipment assets are the [redacted] and the [redacted]. These two individuals at the Miami VA Medical Center have had limited time to work together in order to solve significant challenges. The [redacted] was officially appointed to [redacted] position on December 15, 2008 and was [redacted] preceding her appointment, from July 2008. (FOF 13). In addition, the [redacted] Section, working under the [redacted] has been in [redacted] position since February 2009 (FOF 14) and does not currently have an assistant (FOF 15).
2. The [redacted] has been at the Miami VA Medical Center since August 2004 (FOF 16), and it should be noted that [redacted] has had five supervisors in as many years, since [redacted] arrival. [redacted] originally reported to the [redacted]

[redacted] who changed three times, and was later reassigned to the Associate Director who recently retired. [redacted] currently reports to an Acting Associate Director. (FOF 17).
3. While both the [redacted] and the [redacted] report they have a good working relationship (FOF 18), they both inherited program deficiencies related to management of medical equipment.
4. When the [redacted] arrived at the Miami VAMC in 2004, he found that A&MMS unilaterally controlled the AEMS/MERS system and Biomedical Engineering Service had decided to run a parallel system that also included hard copy maintenance records (FOF 21); evidence of a fundamental lack of cooperation between the two services.
5. Only recently, with the new appointment of the [redacted] has there been a common understanding of the issues they are working to correct, with regard to inventory control and management (FOF 18).

CONCLUSION 2: Procedures for selecting and placing endoscopy equipment and supplies into use are deficient and do not provide for adequate inventory control and maintenance.

ANALYSIS:

1. There was evidence that the Medical Center has a policy for an Equipment Committee (Exhibit O), however, it had not been active for a long period of time and was reconvened in August 2008 (FOF 20).
2. The [redacted], after being appointed to [redacted] new position, described the condition of the equipment inventory lists as being a "disaster." A major effort to improve inventory accuracy was done in December 2008, however, full cooperation of all Services is lacking priority. Equipment thought to be lost, is still being found as recent as March (FOF 19).
3. The [redacted] had a similar assessment of the inventory management, reporting that [redacted] believes there are serious process and control issues (FOF 23). As examples, [redacted] described finding electroencephalography machines named "Hard Drive" in AEMS/MERS and the difficult time he has had over the last couple of years trying to write a service contract for the endoscopes, partially due to the incomplete inventory. [redacted] confidence in the endoscope inventory is described as less than 50% (FOF 27). During the AIB investigation and our focus on the Medivators Endoscope Reprocessors, a [redacted] found three equipment entry numbers for reprocessors, however, there are only two physical units. Inadvertently, an equipment entry number belonging to a vapor management system (a component of the new reprocessor) had been placed on one of the reprocessors and was listed as a washer in the AEMS/MERS inventory (FOF 25; Exhibit KK page 2).
4. Previous to the [redacted], equipment would be delivered straight to using services. Only recently has the proper policy been enforced (FOF 28). The [redacted] estimates that 20% of the time equipment is still delivered directly to users without going through Biomedical Engineering Service, especially if the equipment is mistakenly ordered on a credit card (FOF 26).
5. Although medical equipment receipt and inventory documentation is a responsibility of A&MMS, Biomedical Engineering Service should be intimately familiar

and involved in the process. Improved cooperation between Biomedical Engineering Service and A&MMS will assist in inventory control (FOF 27).
6. Vendor access to the Medical Center was also described as a major problem, whereas, they are able to report through Police Service without having to go through A&MMS (FOF 31). This has allowed for "things coming in through the back door" and a way in which samples can easily be left with users without any organizational oversight (FOF 30).
7. The AIB extracted data from AEMS/MERS, reflecting endoscopes that were designated as "in use" (Exhibit NN) and made comparisons to inventory records maintained by SPD and contained in the Olympus maintenance contract quote (Exhibit JJ). There were numerous discrepancies found and summarized by the AIB in Exhibit NN (FOF 33-36).
8. The GI Nurses have little to no understanding of who is responsible for introducing equipment and supplies into the work site (FOF 37). This finding of fact is what contributed to Byrne Medical, Inc. being able to work directly with the staff to introduce their EndoGator system (Attachment 14) as an alternative to the Olympus MAJ-855 tubing. After initiating use of the system, staff realized that it had not gone through the organization's Commodity Standards Committee for approved use.

Procedures for setting up, using, and processing endoscopy equipment.

CONCLUSION 3: Prior to March 2009, personnel assigned to set up, preclean, and reprocess endoscopy equipment did not utilize appropriate written guidance to perform device-specific duties.
ANALYSIS:
1. Prior to March 23, 2009, procedures for setting up, using, and reprocessing endoscopy equipment were based on past experience and without reference to device specific manufacturers' instructions (FOF 48, 97). Appropriate standard operating procedures did not exist in GI or SPD for staff guidance (FOF 49). New SOPs were put in place on March 23, 2009, but the AIB questions to what degree they have been disseminated and understood by front line staff. The GI SOPs submitted to the AIB were marked draft and not signed (Attachments 10, 11).
2. Staff in GI and SPD had access to manufacturer in-service and competency checklists, along with cleaning guides, however, they are general in nature and should not be used in isolation of any other training or device specific instructions (Attachment 9).
3. SPD did have a scope reprocessing SOP dating back to January 2000, however, it was based on the National SPD Advisory Group's Best Practices and was not modified to device specific instructions (Attachment 10, 11). It was updated on March 24, 2009, yet the AIB determined that it was still summary in nature and did not contain device specific instructions, in comparison to the Olympus Reprocessing Manual (Exhibit OO). In addition, the SOP step 4 of the sterilization process, has an incorrect reference to SOP 3002F for high-level disinfection using Glutaraldehyde based solution (Attachment 11).

CONCLUSION 4: Endoscope reprocessing at the Miami VA Medical Center is deficient and not according to device specific manufacturer's instructions.

ANALYSIS:

1. Employees responsible for endoscope set up, precleaning, and reprocessing do not receive sufficient job-specific training and education to perform these complex and detailed duties (FOF 45, 48, 49, 63, 70-79).
2. There is no process in place to cross-train employees responsible for endoscope set up, precleaning, and reprocessing. For example, the nurses do not have the necessary training to competently set up and preclean the endoscopes even though they are asked to perform the jobs of GI Technicians when they are short-staffed due to vacation and/or illness (FOF 41, 45, 48, 49, 73, 79).
3. The [redacted] expressed concerns about the Medivators Endoscope Reprocessor DSD-201 not completing three (3) rinse cycles due to the printed receipt showing only two (2) rinse cycles. Although the [redacted] testified that Biomedical Engineering Service reviewed the situation and reported to [redacted] that the reprocessor was in fact completing three (3) rinse cycles despite the discrepancy (FOF 65), the [redacted] responsible for the endoscope reprocessors reported that [redacted] was not aware of the discrepancy until March 31, 2009, when the AIB had brought it to the attention of the [redacted]. The [redacted] reported that there are 9 programs that can be selected and that an incorrect program may have been selected for two (2) rinse cycles (Exhibit KK), as [redacted] was able to correct the discrepancy the same day [redacted] became aware of it. It is more likely than not, that the receipts for two (2) rinse cycles are accurate.
4. On March 26, 2009, during a demonstration by an Olympus representative, debris was discovered when manually flushing one of the channels of a clean scope (FOF 126, 128). Forty-four (44) scopes in total were then tested by staff, and the [redacted] documented the results (FOF 127; Exhibit PP).
5. The AIB team reviewed the results (Exhibit PP) and found that discolored fluid and debris were found in biopsy channels in two scopes used in the Operating Room, which are also reprocessed by the [redacted] working in GI (FOF 56). In the AIB's opinion, this was a benchmark for reprocessing issues that were not just limited to endoscopes with the auxiliary water channel feature. The AIB proceeded to conduct a thorough assessment of the reprocessing by the [redacted]
6. On April 1, 2009, an Olympus PCF type H180AL Endoscope was given to [redacted] by the AIB, with instructions to completely reprocess the scope from start to finish. Each step was directly observed, compared to manufacturers' instructions (Exhibit OO, QQ), and documented (Exhibit RR). Findings included a determination that suction equipment was not available to perform certain steps, some steps were incorrect, other steps were omitted, and some of the omitted steps rendered others ineffective even though demonstrated (Exhibit RR).
7. For the direct observation of the reprocessing, the [redacted] did not have available the device specific instructions for the connection of the DSD Endoscope Reprocessor to the endoscope. After the observation, the [redacted] later approached the AIB with DSD-110-HU0068 instructions (Attachment 12) which are for Olympus 130 series endoscopes and below. The AIB obtained the correct instructions

from Medivators' web site, which are DSD-110-HU0161 for Olympus 140 series endoscopes and above (Exhibit QQ). Although both instructions reference the same part number for the auxiliary tubing, during observation of the reprocessing it was determined that the wrong auxiliary tube was used (Exhibit RR). This is further evidence that device specific instructions have not routinely been used in the reprocessing procedures.

Communication among involved programs about equipment inventory, processing endoscopes and maintenance.

CONCLUSION 5: The supervisory structure and communication among involved programs responsible for endoscopy inventory, use, maintenance, and reprocessing is ineffective.

ANALYSIS:

1. Employees having responsibility for endoscope set up, use, precleaning, and reprocessing, have various supervisory chains of command, and most of the oversight of performed work is accomplished with non-supervisory employees (FOF 40, 46).
2. The SPD Technicians responsible for reprocessing endoscopes have a supervisory chain of command to the [redacted], while the GI Technicians, responsible for equipment set up and precleaning, report directly to the [redacted] although [redacted] does not provide direct training to the GI Technicians and has no knowledge of precleaning or set up of equipment (FOF 70). [redacted] defers much of [redacted] supervisory responsibilities to the [redacted] or the [redacted]
3. GI Nurses fill in for GI Technicians on a recurring basis (FOF 41) and have a direct report to the [redacted] (FOF 40), even though the [redacted] does not believe [redacted] has responsibility for "technical issues." (FOF 42). The [redacted] in addition to being responsible for GI, is also supervising the pain clinic, ambulatory surgery, the radiology nurses, and the IV team. With this span of control, [redacted] coordinates work through the nurse liaisons in each area (FOF 43). The [redacted] reports that although [redacted] has never been directly instructed to ensure that procedures are according to manufacturers' instructions, [redacted] feels it is her responsibility (FOF 44), even though [redacted] has never set up a scope, taken it down, or been involved in the precleaning of the endoscopes (FOF 45).
4. Front line staff that are responsible for endoscope set up, precleaning, and reprocessing, all have direct supervisors that have informally delegated their responsibilities to non-supervisory personnel who have insignificant experience with procedures related to endoscopes. This has created an environment where staff are working with general past experience and uncertainty of who is responsible for their quality of work, or even how to define the quality of their work (FOF 63, 75).
5. This supervisory arrangement also contributes to poor communication; specifically, staff utilize various terms for the same equipment and supplies, depending on their area of expertise (FOF 58), and have only compartmentalized understanding of how endoscopes are used and precleaned. For example, [redacted] only became aware of the Patient Safety Alert because of an in-service held in SPD. From SPD's perspective, they understood that the MAJ-855 was not used in their

reprocessing responsibilities, which is where the concerned ended for them. There was no further effort to understand the issues that would fall under other supervisory control. Similarly, the GI Nurses and Technicians understood that they were using the correct tubing according to the Patient Safety Alert, which is where their concern ended. There was no further effort to understand the reprocessing issues that were a responsibility of another Service (FOF 64, 121).

Procedures for educating and training staff in setting up, using and maintaining endoscopy equipment.

CONCLUSION 6: Supervisors of personnel assigned to set up, preclean, and reprocess endoscopy equipment do not ensure device-specific training or perform associated competency assessments. The supervisors do not have the knowledge, skills, or abilities to train or assess competency.

ANALYSIS:

1. The [redacted], [redacted], and [redacted] interviewed by the AIB have been in their respective positions from 7 years to 1-1/2 years, and each described an absence of device specific SOPs for the work they performed, prior to March 2009 (FOF 48, 49, 73, 74, Attachment 10, 11). In addition, they describe their work as being based on experience and instructions given by past preceptors (FOF 48, 73, 74). The [redacted] orientation and training consisted of [redacted] observing a previous SPD Technician for one week, and then being observed for one week, prior to independently performing [redacted] duties (FOF 74).
2. The direct supervisors, and non-supervisors who are relied on to oversee work, have not received device specific training or understand that the technical aspects of set up, precleaning, and reprocessing are part of their responsibility (FOF 70-75).
3. Competency assessments for endoscopy set up, precleaning, and reprocessing, are either non-existent or sufficiently abbreviated to render them ineffective. For the SPD Technicians and immediate supervisor there was no recorded evaluation for FY08, just an evaluator's signature, and in the assessment of the direct supervisor, it was self-certified (FOF 76-79; Exhibit FF). The [redacted] does not perform competencies on endoscope precleaning and relies on staff's on-the-job experience (FOF 79). The competency assessments reviewed by the AIB did not meet the intent of the Medical Center Policy (Exhibit Q).
4. The Olympus representative came to the facility on March 26, 2009 to provide training, however, based on the number of individuals in attendance and the fact that training did not include employee hands on participation with an assessment of their competency, the AIB finds that the session was more appropriately characterized as a demonstration by the manufacturer (FOF 126, 128).

Procedures to respond to recalls and alerts.

CONCLUSION 7: The Miami VAMC organization does not have a clear process or understanding of how recalls and patient safety alerts should be processed. As a result, incomplete information and erroneous information is provided to Leadership for decisions.

ANALYSIS:

1. The AIB found that the Miami VAMC did have a policy in place for handling Patient Safety Alerts (Exhibit LL) with assignments of responsibility, but the policy was outdated (FOF 11). Per policy, the Director's office notifies the Service or Product line with primary responsibility for the Patient Safety Alert, however, a parallel system of routing is established from the [redacted] to the facility's [redacted], who also identifies individuals with responsibilities for the Patient Safety Alert. Having dual processes for Patient Safety Alert responses is potentially confusing and problematic (FOF 91, 92).
2. Some of the key staff did not understand the process for responding to Patient Safety Alerts, and a critical member of the recall process did not know who the designated Facility Recall Coordinator was (FOF 87, 88). The [redacted] responsible for coordinating the Patient Safety Alerts, understood the process the best, but still described the structure for responding to them as problematic (FOF 92). The original routing of the Patient Safety Alert did not include the [redacted] who also feels that a good process is not in place for handling Patient Safety Alerts (FOF 81).
3. As a result, A&MMS responded to the Patient Safety Alert 09-07, with little cooperation of other involved Services and did not accurately report compliance with the alert (Exhibit K).

Practices prior to the issuance of Patient Safety Alert 09-07, as well as the medical center's response to the Alert.

CONCLUSION 8: Practices prior to the issuance of Patient Safety Alert 09-07 were not in full compliance with device specific requirements that the alert was intended to address.

ANALYSIS:

1. In reference to the Olympus diagram of the scope, tubing, and Olympus Flushing Pump (Exhibit J), the Miami VAMC was utilizing the correct auxiliary water tube (MAJ-855) (Exhibit D, G, H); however, they were not following manufacturers' instructions for intervals of component reprocessing. The GI Technicians and GI Nurses were not aware that the tubing or other components of the Olympus Flushing Pump system required reprocessing, and only flushed/rinsed the components (FOF 50, 93).
2. With regard to conclusion 3, and manufacturers' instructions for reprocessing (Exhibit A, G, H, OO, SS; FOF 53), the AIB team found the endoscope reprocessing to be deficient (Exhibit RR).

CONCLUSION 9: The Medical Center's response to Patient Safety Alert 09-07 was prompt and well intended, however, poor communication and a lack of due diligence by supervisors resulted in an erroneous report of compliance.

ANALYSIS:

1. Patient Safety Alert 09-07, dated December 22, 2008, was received by the Facility [redacted] through the VHA Hazard Alert distribution. The [redacted] was on leave December 23, 2008 and distributed the alert to the organization on December 24, 2008. The distribution included all immediate and higher level supervisors for those having responsibility for endoscopes (Exhibit K, MM). It was sent for informational purposes to the individuals on the distribution list, with an understanding that the [redacted] had the responsibility for responding to the alert (FOF 100). The AIB team determined that the organization did recognize the [redacted] as having responsibility for responding to the alert, but there was no clear documentation that an assignment had been made. The understanding came more from past practice, and the fact that the Patient Safety Alert was in reference to endoscope reprocessing.
2. The [redacted] asked the [redacted] to look into the alert, who then ran a search in the item master file to determine if the MAJ-855 tubing had ever been purchased. The [redacted] also ran the search (FOF 103). The [redacted] reports that he also contacted GI and asked if they had the "pump", however, [redacted] could not recall who he spoke to. [redacted] summarized it by saying "word got back to us" that the pump was not used in the GI Station (FOF 102). The [redacted] states that [redacted] was never contacted by anyone in regards to the Patient Safety Alert and [redacted] is unaware of anyone else in [redacted] Section being contacted (FOF 105). With an incorrect understanding that the pump was not used at the facility and the fact that [redacted] search showed no purchases of the MAJ-855 tubing, the [redacted] reported to the [redacted] who in turn reported to the [redacted] The [redacted] was not satisfied with the initial response and [redacted] felt that it was too abbreviated, so [redacted] asked for more documentation to show that all three action items were completed (FOF 104). The [redacted] responded in an email on January 5, 2009, that all three action items were completed, and that the Medical Center did not use the Olympus Flushing Pump (FOF 103, 104, 101, Exhibit MM).
3. The AIB also noted that the MAJ-855 tube comes with each new scope purchase (Attachment 15); therefore, there were a number of these tubes at the Medical Center. Considering the fact that the tubing wasn't being reprocessed, there was sufficient inventory that would have delayed any replacement orders, which is most likely why a search of the item master file indicated that the MAJ-855 tubing had never been ordered.
4. The response from the [redacted] and the [redacted] reflects a lack of due diligence in assessing how the Patient Safety Alert applied to the organization. The AIB team notes that the Olympus Flushing Pumps were in the AEMS/MERS inventory and a search would have easily discovered them (Exhibit NN). In addition, a simple walk through of the GI Station with direct observation of equipment would also have led to the understanding that the pump was used.
5. Both the [redacted] and the [redacted] understood the absence of the MAJ-855 tubing in the item master file as support for their conclusion that most of the Patient

Safety Alert did not apply to Miami. This is only logical in the context of not having the pump, otherwise it should intuitively have been a red flag, since the Patient Safety Alert is pointing out that the MAJ-855 is the correct tubing to use with the Olympus Flushing Pump (FOF 102, 103; Exhibit D).

6. The [redacted] had forwarded the Patient Safety Alert to the [redacted], for a determination if a problem existed (FOF 108). The [redacted], also received the Patient Safety Alert via email from the [redacted], however, [redacted] did not understand or infer that [redacted] had any responsibility for the Patient Safety Alert (FOF 105). Both [redacted] and the [redacted] relied on the GI Nurses for a determination of compliance (FOF 106, 108). The GI Nurses and [redacted] became aware of the Patient Safety Alert indirectly, and without assignments. They each determined that they were in fact using the correct tubing called for in the Patient Safety Alert; the MAJ-855, however, they did not deal with the reprocessing issue (FOF 106-111).

7. The [redacted] first became aware of the MAJ-855 reprocessing issue when a representative from Byrne Medical, Inc. made a visit on February 13, 2009 and brought the Olympus Safety Alerts (Exhibits E&F) to [redacted] This is when the EndoGator system was introduced as an alternative to the MAJ-855 tubing. It was previously noted by the AIB that the EndoGator system was used prior to Commodity Standards Committee approval (FOF 120). The EndoGator system was not used in accordance with manufacturers' instructions, since the system was understood to be a unit that is disposed of at the end of the day (Exhibit TT). The Manufacturer however, indicates that the back flow valve (Attachment 14, purple part) is to be replaced between every patient (Exhibit HH).

8. On March 12 & 13, 2009, the [redacted] as part of Endoscope "Step-Up Week", reviewed the Patient Safety Alert 09-07 a second time and examined it closely, which is when [redacted] understood that the Patient Safety Alert was also referring to the reprocessing issue of the MAJ-855 (FOF 111).

9. The compartmentalized approach to the Patient Safety Alert led to an erroneous report of compliance.

[redacted] DATE:_____

[redacted] DATE:_____

[redacted] DATE:_____

[redacted] DATE:_____

[redacted] DATE:_____

[redacted] DATE: 4.23.09

[redacted]

Department of Veterans Affairs

Memorandum

Date: April 25, 2009

From: Chair, Administrative Investigation Board (AIB) (00/531)

Subj: AIB Executive Summary and Report Transmittal: Issues Related to Endoscope Reprocessing at the Miami VAMC.

To: Network Director VISN 8 (10N8)

1. The AIB team convened by your authority is pleased to provide you with the completed report on endoscope reprocessing issues at the Miami VA Medical Center, which is attached to this transmittal memorandum. An original signature page is being routed to all members and you should receive it within the next two weeks.

2. As Chair of the AIB, I want to personally thank you for your insight and forethought given to the selection of team members. Without exception, each member was highly skilled, engaged, and was a strong contributor from day one.

3. It was not our charge to provide recommendations as part of our investigation; however, we would be remiss in not sharing some of our thoughts as we look back on our efforts. I would like to preface those thoughts by recognizing the Miami staff - everyone we met was very cooperative, forthcoming, and dedicated to the Veteran.

a. Industry Complexity: It is important to realize just how complex the industry has become with regard to endoscopes, related accessories, and reprocessing equipment. The AIB found the required skill level, dedicated time, and training, necessary to assure compliance with manufacturers' instructions to be immense. The AIB team's opinion is that the industry bears some responsibility in reducing the complexity and burden on the users of their products.

b. One of the findings of fact is that the [redacted], does not have an Assistant Chief. It is our understanding that this is a mandated position by VACO for complexity 1 facilities. This is offered as a topic of discussion for resource management and prioritization.

c. The AIB did not focus on equipment inventory specific to Information Technology (IT); however, we did come away with an understanding that there is concern over the inventory management of IT equipment. This topic may need further review and analysis by VISN 8 or local leadership.

d. As our report points out, there is a common understanding of what the issues are between the [redacted] and the [redacted], with both describing a cooperative working relationship. It is worth noting that A&MMS controls the initial entries and changes to the AEMS/MERS equipment inventory file. Although Biomedical Engineering Service does provide input to A&MMS for medical equipment entry and error corrections, the process is not as effective as it could be. Biomedical Engineering Service should have control over certain fields in the AEMS/MERS inventory file, such as the Equipment Category, which is the field critical to the preventive maintenance program and Joint Commission compliance. The current arrangement between the two Services does not lend itself to efficient and timely correction of errors in the inventory. With some additional resources (i.e. bar code scanners/printers) and a new agreement on how to share the AEMS/MERS inventory between the two services, it is reasonable to expect a significant improvement in medical equipment inventory within a shorter period, as compared to moving forward with the status quo.

e. The AIB report documents concern with vendor access to the Medical Center. The [redacted] reported that the policies and procedures in place for vendor access to the Operating Rooms are complete and in force. Due to the concerns of general vendor access to the Medical Center, it would be due diligence to specifically review vendor access in the context of the Operating Rooms, to determine the effectiveness of the current procedures for controlling vendors.

f. The AIB noted the number of scopes reprocessed by the SPD Technicians in a single day. It is recommended that workload be carefully reviewed in total, to ensure that Technicians are working within their abilities. An unreasonable workload can directly or indirectly result in incomplete reprocessing.

g. It does not appear that the Endoscope Reprocessors are being maintained properly. It is recommended that supervisors review the manufacturer requirements for both user maintenance and Biomedical Engineering maintenance. There should be a team effort to ensure proper maintenance of this equipment, with a clear understanding of who is performing the different maintenance requirements with documentation of work performed.

h. The GI Nurses, GI Technicians, and SPD Technicians in GI report they are not members of their professional organization, the Society of Gastrointestinal Nurses and Associates (SGNA), have not participated in SGNA regional and national continuing medical education activities, have not taken SGNA certification examinations, and do not regularly read manufacturer's manuals and instructions. SGNA Membership and certification is not required of the position by qualification or PD/functional statement but there is strong wording in the nursing qualification standards for specific grades that would almost equal "requirement" as in providing evidence-based patient care. Participation in education and review of current literature with application to one's field of practice is mandatory. Thus, it is recommended by the AIB that those working in GI attend continuing medical

education activities sponsored by the organization and strive to become members in and obtain certification from the organization. Furthermore, GI Endoscopy is complex, highly technical and ever changing; and subject matter experts are not present in the VA facilities, with perhaps the exception of GI in some places. Even the experts need to continually update their knowledge. It is also recommended that time be set aside each week to read and review the GI Endoscopy published literature, society guidelines, manuals, and manufacturers' device specific instructions.

Also of note, the International Association of Healthcare Central Service and Materiel Management (IAHCSMM) is the professional organization for SPD and has certification testing available to its members. VHA SPD has its own certification program as well. Both SGNA and the Certification Board for SPD (CBSPD) have certification applications specific to endoscope reprocessing.

i. As the AIB report illustrates, there is a lack of communication and coordinated chain of command among the disparate departments servicing the GI Endoscopy Unit. It is a recommendation of the AIB that a Nurse Manager be uniquely assigned to GI Endoscopy as a clinical specialist in all aspects of GI Endoscopy. The Nurse Manager should have limited administrative duties, allowing a focus on competencies, continued education for the staff (GI Nurses, GI Technicians, and GI scope reprocessors), as well as reading and understanding all manufacturer's instructions regarding reprocessing, operations, and service. In addition, an Administrative Officer for GI is recommended, who would oversee and coordinate the administrative and clinical workload for the GI Section, including the Endoscopy unit, and facilitate coordination amongst the GI Nurses, GI Technicians, and GI scope reprocessors. The Administrative Officer would relieve some of the administrative workload from the Nurse Manager, enabling the Manager to function as a "hands on" clinical specialist.

4. If there are any comments, questions, or concerns related to our assignment, please do not hesitate to contact me at 208-422-1300.

[redacted]

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